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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/945,238	08/31/2001	Werner G. Kuhr	407T-300200US	1309

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EXAMINER	
BABIC, CHRISTOPHER M	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 12/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/945,238	KUHR ET AL.	
	Examiner	Art Unit	
	Christopher M. Babic	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) 22-67 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-21 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 31 August 2001 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 7/21/03; 10/24/02, 8/29/02, 3/29/02; 3/25/02, 2/25/02
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

It is noted that the Examiner and art unit of record has changed in the current prosecution of the instant application. The instant application has been transferred to art unit 1637 in TC1600, and will be further examined by Christopher M. Babic.

Election/Restrictions

Applicant's election of Group I, Claims 1-21, in the reply filed on September 6, 2005 is acknowledged. Because applicant did not distinctly and specifically point out any supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 26, 29, and 30 of Mathies et al. (U.S. 6,361,671).

Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 26 of Mathies et al. ('671) sets forth a method of determining the sequence of a DNA template that comprises the steps of: (a) generating and redox labeling all possible complementary sequencing fragments of the DNA template to be sequenced where the sets of fragments terminating with the four different bases (A,C,G,T) are identified by distinct electrochemical signals generated by the redox label associated with each of the distinct sets or fragments; (b) electrophoretically separating said sets of labeled fragments in single channel or lane; and (c) simultaneously detecting the distinct electrochemical signals generated by the redox labels to identify the individual fragments. Claims 29 and 30 further disclose simultaneous, as well as sinusoidal voltammetric detection. Claim 1, and any claims dependent thereof, encompass the same general inventive concept of Claims 26, 29, and 30 of Mathies et al.

('671) by incorporating redox labeling, separation, and various voltammetric detections.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-7, 11, 12, 20, and 21 are rejected under 35 U.S.C. 102 (b) as being anticipated by Mathies et al. (WO 00/42424).

With regard to Claims 1 and 2, Mathies et al. disclose a method of determining the sequence of a DNA template (Page 7, Line 26-Page 8, Line 23, for example) that comprises the steps of: (a) generating and redox labeling all possible complementary sequencing fragments of the DNA template to be sequenced where the sets of fragments terminating with the four different bases (A, C, G, T) are identified by distinct electrochemical signals generated by the redox label associated with each of the distinct sets or fragments; (b)

electrophoretically separating said sets of labeled fragments in single channel or lane; and (c) simultaneously detecting the distinct electrochemical signals generated by the redox labels to identify the individual fragments (Page 23-24, Claim 26, for example). They further disclose cyclic voltammetry (Page 13, Lines 25-30, for example). They further disclose sinusoidal voltammetry including the harmonic isolation and digital phase locking of electrochemical signals (Page 14, Lines 5-20, for example).

With regard to Claims 3-6, Mathies et al. disclose dideoxy chain termination methods wherein primers and terminators can be labeled with redox labels (Page 9, Lines 5-20, for example).

With regard to Claim 7, Mathies et al. disclose metalloporphyrins (Figure 10B; Page 16, Lines 20-30, for example).

With regard to Claim 11, Mathies et al. disclose voltammetric detection at one electrode (Page 22, Lines 15-20, for example).

With regard to Claim 12, Mathies et al. disclose sinusoidal voltammetry (Page 14, Lines 5-20).

With regard to Claims 20 and 21, Mathies et al. disclose electrophoretic and chromatographic separation methods (Page 8, Lines 1-5, for example).

2. Claims 1-7, 11, 12, 20, and 21 are rejected under 35 U.S.C. 102 (e) as being anticipated by Mathies et al. (U.S. 6,361,671).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

With regard to Claims 1 and 2, Mathies et al. disclose a method of determining the sequence of a DNA template (Columns 3,4; Columns 14,15, Claims 26-34, for example) that comprises the steps of: (a) generating and redox labeling all possible complementary sequencing fragments of the DNA template to be sequenced where the sets of fragments terminating with the four different bases (A, C, G, T) are identified by distinct electrochemical signals generated by the redox label associated with each of the distinct sets or fragments; (b) electrophoretically separating said sets of labeled fragments in single channel or lane; and (c) simultaneously detecting the distinct electrochemical signals generated by the redox labels to identify the individual fragments (Columns 14,15, Claim 26, for example). They further disclose cyclic voltammetry (Column 9, Lines 15-25, for example). They further disclose sinusoidal voltammetry including the harmonic isolation and digital phase locking of electrochemical signals (Column 9, Lines 30-55, for example).

With regard to Claims 3-6, Mathies et al. disclose dideoxy chain termination methods wherein primers and terminators can be labeled with redox labels (Column 6, Lines 15-40, for example).

With regard to Claim 7, Mathies et al. disclose metalloporphyrins (Figure 10B; Column 11, Lines 15-25, for example).

With regard to Claim 11, Mathies et al. disclose voltammetric detection at one electrode (Column 14, Lines 25-30, for example).

With regard to Claim 12, Mathies et al. disclose sinusoidal voltammetry (Column 9, Lines 30-55, for example).

With regard to Claims 20 and 21, Mathies et al. disclose electrophoretic and chromatographic separation methods (Column 5, Lines 25-35, for example).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathies et al. (WO 00/42424) in view of Ihara et al.

"Ferrocene-oligonucleotide conjugates for electrochemical probing of DNA" Nucleic Acids Research. 1996. Vol. 24, No. 21: Pages 4273-4280).

With regard to Claims 8 and 9, the methods disclosed by Mathies et al. have been outlined in the above rejections. Mathies et al. do not specifically disclose the use of ferrocene as a redox-active label.

Ihara et al. disclose the use of electrochemically active oligonucleotides prepared by covalent linkage of a ferrocenyl group to the 5'-amino-hexyl-terminated synthetic oligonucleotides (Abstract; Figure 1; Pages 4274-4276, materials and Methods).

Ihara et al. further disclose the ferrocene-modified oligonucleotides proved to be promising probes for microanalysis of DNA because of their facile procedure for detection, outstanding sensitivity, and invariant response for the target structures and sequences (Page 4820, Column 1, Paragraph 1).

Based on the combined disclosures of the applied references, one of ordinary skill in the art at the time of invention would have had a reasonable expectation of success practicing the methods of Mathies et al. further comprising the use of ferrocene as a redox-label. The motivation to do so, provided by Ihara et al., would have been their ease of use as probes for microanalysis of DNA. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of invention to practice the instant methods as claimed.

2. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mathies et al. (WO 00/42424) in view of Nishino et al. "Synthesis of Linear Amphipathic Porphyrin Dimers and Trimers: An Approach to Bilayer Lipid Membrane Spanning Porphyrin Arrays" Journal of Organic Chemistry. 1996. Vol. 61: Pages 7534-7544).

With regard to Claim 10, the methods disclosed by Mathies et al. have been outlined in the above rejections. Mathies et al. do not specifically disclose the use of a porphyrinic macrocycle as a redox-active label.

Nishino et al. disclose the use of "meso" substituted porphyrinic macrocycles in the construction of porphyrin arrays (Abstract; Scheme 1; Pages 7541-7544, Experimental Section).

Nishino et al. further disclose meso-perfluroinated substituents at two of the four meso-positions would be attractive for imparting hydrophobic character to the porphyrins (Page 7535, Column 1, Paragraph 2).

Based on the combined disclosures of the applied references, one of ordinary skill in the art at the time of invention would have had a reasonable expectation of success practicing the methods of Mathies et al. further comprising the of a porphyrinic macrocycle as a redox-active label. The motivation to do so, provided by Nishino et al., would have been to impart hydrophobic character to the porphyrins for the purpose of constructing porphyrinic arrays. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of invention to practice the instant methods as claimed.

3. Claims 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathies et al. (WO 00/42424) in view of Kuhr et al. (U.S. 5,650,061).

With regard to Claims 13-19, the methods disclosed by Mathies et al. have been outlined in the above rejections. Mathies et al. do not specifically disclose performing a Fourier Transform, selecting voltammetric data at a second or higher harmonic frequency, or selecting voltammetric data at specific phase angels.

With regard to Claims 13-15, Kuhr et al. disclose converting voltammetric data through a Fourier Transform (Column 4, Line 60-Column 5, Line 8; Column 15, Lines 25-30, for example).

With regard to Claims 16-18, Kuhr et al. selecting voltammetric data at a second or higher harmonic frequency (Column 15, Lines 35-45, for example).

With regard to Claims 18 and 19, Kuhr et al. disclose quantifying a current from an analyte at a selected phase angle of measurement to enhance a detected signal corresponding to a redox species of interest (Column 16, Lines 1-15).

Based on the combined disclosures of the applied references, one of ordinary skill in the art at the time of invention would have had a reasonable expectation of success practicing the methods of Mathies et al. further comprising performing a Fourier Transform, selecting voltammetric data at a

second or higher harmonic frequency, or selecting voltammetric data at specific phase angels. At the time of invention, the disclosure of Kuhr et al. clearly would have provided the instruction necessary for one of ordinary skill in the art to practice the methods as claimed. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of invention to practice the instant methods as claimed.

Conclusion

No claims are allowed. No claims are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 571-272-8507. The examiner can normally be reached on Monday-Friday 7:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through

Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

11/28/05

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